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Ī	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.	
	09/036,614	03/07/98	B HILLMAN	Ţ	*FF-0484US	
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HM21/1202

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EXAMINER					
GUCKER, S					
ART UNIT	PAPER NUMBER				
1645	4				

DATE MAILED:

12/02/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Serial Number: 09/036,614

Art Unit: 1645

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-2 and 13, drawn to a polypeptide and polypeptide compositions, classified in class 530, subclass 350, for example.

Group II. Claims 3-12, drawn to a polynucleotide, classified in class 536, subclass 23.5, for example.

Group III. Claim 14, drawn to an antibody, classified in class 530, subclass 387.1, for example.

Group IV. Claim 15, drawn to an agonist, classified in class 514, subclass 1+, for example.

Group V. Claim 16, drawn to an antagonist, classified in class 514, subclass 1+, for example.

Group VI. Claims 18-19, drawn to treatment methods, classified in class 514, subclass 12, for example.

Group VII. Claims 20-21, drawn to a method of detection, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for "inventive groups that are directed to <u>different</u> products; restriction is deemed

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following reasons:

to be proper because these products appear to constitute patentably distinct inventions for the

Groups I-V are directed to products that are distinct physically, structurally, and functionally, and are therefore patentably distinct, each group from the other, and are not required one for the other. The polypeptide of Group I can be made recombinantly with the polynucleotide of Group II or purified from its natural source with the antibody of Group III. The polynucleotide of Group II can be used to make the polypeptide of Group I or can be used as a probe with the methods of Group VII. The antibody of Group III can be used to isolate the polypeptide of Group I or it can be used in a method of detection. The agonist or antagonist of Groups IV or V are functionally the opposite of each other, bear no structural or physical realationship to each other, and are not required, one for the other.

- 3. Groups I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I can be used to raise antibodies and it can be used in a method of treatment.
- 4. Groups II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed

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can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group II can be used to make a polypeptide and it can be used in a method of detection.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for "inventive groups that are directed to <u>different</u> methods; restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

Groups VI and VII are directed to methods that comprise distinct process steps (method of treatment, method of detection) and use distinct products (polypeptide, polynucleotide) that are different physically, structurally, and functionally, and are therefore patentably distinct, each group from the other, and are not required one for the other.

- 6. Any of the products of Groups III-V are not used in or produced by any of the methods of Groups VI-VII. The product of Group I is not used in or produced by the method of Group VII.

 The product of Group II is not used in or produced by the method of Group VI.
- 7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate classifications and because the literature searches required for the inventions are not co-extensive and therefore references that would anticipate one invention would not necessarily anticipate or even make obvious the other invention, a search burden exists, and restriction for examination purposes as indicated is proper.

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Furthermore, there are different issues for the search and examination of each, which would also be unduly burdensome.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

- 8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).
- 9. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend

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the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Any inquiry concerning this communication or earlier communications from the examiner 10. should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Thursday from 0730 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephen Gucker

December 2, 1998

ANTHONY C. CAPUTA PRIMARY EXAMINER